

[OPTS-42001; TSH-FRL-1979-6]

**Benzidine-, O-Tolidine- and O-Dianisidine-Based Dyes Response to the Interagency Testing Committee**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Interagency Testing Committee, established under section 4(e) of the Toxic Substances Control Act, designated benzidine-, o-tolidine- and o-dianisidine-based dyes for health and environmental effects testing as published in the Federal Register of December 7, 1979 (44 FR 70665). EPA has decided not to pursue sec. 4(a) testing proposals for these chemicals at this time because testing programs which are expected to supply data sufficient for the Agency's needs are being currently planned and conducted, and regulatory efforts are being pursued. Therefore, acting pursuant to section 4(e) of TSCA, EPA is publishing this notice of its decision not to require additional testing as its response to these three ITC recommendations. EPA will retain the right to require additional testing at a later time should the circumstances so warrant.

**FOR FURTHER INFORMATION CONTACT:**

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## SUPPLEMENTARY INFORMATION:

## I. Background

Section 4(a) of TSCA authorizes the Administrator of EPA to promulgate regulations requiring testing of chemical substances and mixtures in order to develop data relevant to determining the risks that such chemicals may present to health and the environment.

Section 4(e) of TSCA established an Interagency Testing Committee to make recommendations to the Administrator of EPA of chemicals that should receive priority consideration for proposing test rules under sec. 4(a). The Committee may at any one time designate up to 50 of its recommendations for special attention by EPA. Within 12 months of that designation, EPA must initiate rulemaking to require testing or publish in the Federal Register reasons for not doing so.

Benzidine and its congeners *o*-toluidine and *o*-dianisidine constitute a family of synthetic organic chemicals with a biphenyl moiety. These three parent amines (benzidine, *o*-toluidine and *o*-dianisidine) are precursors used in the synthesis of dyes collectively referred to as the benzidine congener dyes. There are now commercially available in the United States 22 benzidine-based dyes, 34 *o*-dianisidine-based dyes, 22 *o*-toluidine-based dyes, and 2 dianisidine-based pigments. The technology exists for producing more than 450 dyes and pigments (Phase I Document, EPA) that are based on benzidine or the benzidine congeners.

The ITC recommended benzidine-, *o*-toluidine- and *o*-dianisidine-based dyes for health and environmental effects testing as published in the Federal Register of December 7, 1979 (44 FR 70665). The benzidine-based dyes were recommended for environmental fate and effects testing, while *o*-toluidine and *o*-dianisidine-based dyes were recommended for general human health effects testing and environmental fate and effects testing. The ITC did not recommend health effects testing for benzidine-based dyes because these dyes were considered to be an established health hazard. However, the ITC suggested that more careful investigations in the area of general health effects are necessary to determine the potential adverse health effects of the *o*-toluidine and *o*-dianisidine-based dyes. This was based upon the uncertainty of the metabolic fate of each dye in these categories and the carcinogenic potential of the parents, *o*-toluidine and *o*-dianisidine.

The primary basis for the environmental testing recommendations was the need for clarification of the environmental biodegradation products

of the benzidine congener dyes. The ITC was concerned that these dyes may be environmentally converted to their respective parent amines or other substituted derivatives. The ITC also indicated that a sequenced approach be used to evaluate potential environmental effects using the results of environmental fate studies.

In the Federal Register of August 12, 1980 (45 FR 53672), OSHA published "A List of Substances Which May be Candidates for Further Scientific Review." These candidates included a list of chemical substances having substantial evidence of carcinogenicity compiled by the Carcinogen Assessment Group, EPA. The Carcinogen Assessment Group identified the parent amines of the benzidine congener dyes, benzidine, *o*-toluidine and *o*-dianisidine, as having substantial evidence of carcinogenicity. Therefore, if adequate evidence is provided that the benzidine congener dyes are metabolized or biodegraded to their respective carcinogenic parent amines, then the dyes may present a potential health hazard.

## II. Basis for the Decision not to Require Additional Testing

This notice removes from the Agency's priority list established under sec. 4(e) of TSCA the ITC's designation of benzidine-, *o*-toluidine- and *o*-dianisidine-based dyes for environmental fate and effects testing, and of *o*-toluidine- and *o*-dianisidine-based dyes for health effects testing. While the data available at this time may be insufficient to characterize completely all the adverse health and environmental effects of the benzidine congener dyes, the present and planned testing is expected to provide information from which these effects can reasonably be determined or predicted, thus addressing the ITC's major concerns. This and several additional reasons have led to EPA's decision not to initiate rulemaking under section 4(a) for these chemicals at this time.

## A. Testing Programs

A significant amount of environmental and health-related testing is being sponsored by the Federal Government and private industry which will address the ITC testing recommendations. The National Toxicology Program (NTP), Consumer Product Safety Commission (CPSC), National Center for Toxicological Research (NCTR), National Institute for Occupational Safety and Health (NIOSH), Dyes Environmental Toxicology Organization,

Inc. (DETO), and the Ecological and Toxicological Association of the Dyestuffs Manufacturing Industry (ETAD) have either completed and published their research efforts or are developing research programs related to the benzidine congener dyes.

The health effects testing recommendations made by the ITC will be addressed by the combined research efforts of NCTR, NIOSH, NTP and CPSC. NCTR, NIOSH, NTP and CPSC are jointly conducting metabolic studies, including absorption, distribution and excretion patterns of selected radiolabeled and non-radiolabeled benzidine congener dyes and their respective parent amines. In further recognition of the ITC testing recommendations, genetic toxicology testing using the modified Ames *Salmonella* screen and *in vivo* carcinogenic bioassays will be performed by NTP on selected benzidine congener dyes and their respective parent amines. These studies are designed to identify the carcinogenic or the mutagenic potential of the chemicals tested.

The ITC environmental testing recommendations will be addressed by ETAD and EPA testing programs. ETAD is developing standard environmental testing methodologies and conducting studies on fish toxicity and bioaccumulation, environmental biodegradation, and bacterial, i.e. sewage sludge, inhibition by dyestuffs. Other current research efforts are those of EPA's Office of Solid Waste, which, in conjunction with the Industrial Environmental Research Laboratory, at Research Triangle Park, North Carolina, is conducting a study to identify the chemicals in solid waste streams produced by the manufacture of dyes and pigments based on benzidine and benzidine congeners. Completion of this study, which will quantify significant amounts of chemical wastes produced by dye manufacturers, is expected in 1981.

These industrially and Federally sponsored tests are designed to investigate thoroughly the potential adverse health and environmental effects of the benzidine congener dyes. The health effects and environmental fate and effects testing recommended by the ITC will be performed by the investigations that are now being conducted or will be conducted on these dyes. While some additional tests beyond those recommended by the ITC might be desirable, it is the Agency's judgment that the amount of useful information which could be gained from additional experiments would be small in comparison with the data already

being developed. Furthermore, any additional test may not serve a useful purpose because the results of the tests may duplicate information from investigations now being performed. Although EPA is not requiring any further testing of the benzidine congener dyes, under section 8(d) of TSCA unpublished health and safety studies about these dyes will be required to be submitted to EPA by industry. Any additional health and safety information submitted to EPA by industry in response to section 8(d) of TSCA will help to characterize more adequately the benzidine congener dyes and help prevent future testing duplication.

### B. Regulatory Efforts

In addition to the significant amount of testing that is now being conducted or that will be conducted with respect to these chemicals, CPSC, the Occupational Safety and Health Administration (OSHA), NIOSH and EPA have developed major regulatory approaches for the benzidine congener dyes. The combined efforts of these regulatory agencies are intended to substantially reduce exposure to these dyes in occupational environments, from consumer products and in the general ambient (water, air, land) environment.

Based primarily on the carcinogenicity of the dyes, CPSC has voted to pursue preliminary regulatory activities to ban the benzidine congener dyes from consumer products (Briefing Package on Benzidine Congener Dyes to the Commission, September 1980). In addition, NIOSH and OSHA jointly recommended that the manufacture and use of benzidine congener dyes be handled as potential carcinogens and that safe dyes be substituted when available (*Health Hazard Alert: Benzidine, o-Tolidine, and o-Dianisidine-Based Dyes*, December 1980).

In accordance with the Federal Water Pollution Control Act (P.L. 92-500, 33 U.S.C. 1251) as amended, EPA has recently completed an Ambient Water Quality Criteria Document for Benzidine (U.S. EPA, October 1980). EPA determined that the benzidine concentrations in ambient water should be zero, based on the non-threshold assumptions for chemical carcinogens. Since zero exposure levels may not be technologically attainable at the present time, the recommended ambient water concentrations for benzidine is very low (expressed in low nanogram concentrations).

### III. Conclusion

The EPA has decided not to require additional testing for benzidine, o-

tolidine and o-dianisidine-based dyes at this time.

First, significant amounts of environmental and health testing have been conducted or are being planned. The National Toxicology Program has coordinated its testing program with EPA, CPSC and OSHA. The private industrial sector is also involved with various testing programs. These Federal and industrial investigations have been designed to identify the potential adverse health and environmental effects of the benzidine congener dyes. These investigations appear to address the ITC's testing recommendations. The Agency believes that any additional information that might be obtained from an EPA test rule would be small in comparison with that now being developed.

Second, CPSC's, EPA's and OSHA's/NIOSH's regulatory efforts are designed to reduce substantially consumer exposures, environmental concentrations and occupational exposures to the benzidine congener dyes that might generate any adverse effects.

Given these facts, EPA has decided not to initiate rulemaking to require testing of benzidine-, o-tolidine- and o-dianisidine-based dyes under section 4(a) at this time.

Should the test results from the ongoing or planned testing, or any other information brought to the attention of EPA indicate concerns which are not adequately addressed by the ongoing activities, EPA will reconsider the need to initiate a testing rule under section 4(a) of TSCA.

### IV. Public Record

EPA has established a public record for this action, docket number OPTS-42001, which is available for inspection in the OPTS Reading Room from 8:00 a.m. to 4:00 p.m. on Monday through Friday, Rm E-107, 401 M St., SW, Washington, D.C. 20460.

This record includes basic information considered by the Agency in developing this notice. The Agency will supplement the record with additional information as it is received. The record includes the following information:

(1) Federal Register notices pertaining to this rule:

(a) Notice of Response to the Interagency Testing Committee published in the Federal Register of November 5, 1981.

(b) Fifth Report of the Interagency Testing Committee to the Administrator, Environmental Protection Agency. Receipt of the Report and Request for Comments Regarding Priority List of Chemicals (44 FR 70664).

(c) A List of Substances which may be Candidates for Further Scientific Review and Possible Identification, Classification, and Regulation as Potential Occupational Carcinogens (45 FR 53672).

(d) Identification and Listing of Hazardous Waste (44 FR 33119).

(e) Toxic Pollutant Effluent Standards, Standards for Benzidine: Final Decision (42 FR 2917).

(2) Supporting documents:

(a) NTP Benzidine Congener Dye Initiative.

(b) Ecological and Toxicological Association of the Dyestuffs Manufacturing Industry, Annual Report, 1979.

(c) TSCA Chemical Assessment Series, Preliminary Risk Assessment: Phase I, Benzidine, Its Congeners, and Their Derivative Dyes and Pigments, June 1980, EPA-560/11-80-019.

(d) The Carcinogen Assessment Group's List of Carcinogens, July 14, 1980.

(e) Proposal and Work Schedule for Research Concerning Metabolism of Benzidine and Benzidine Congener-Based Azo Dyes for NTP, October 16, 1980.

(f) Draft Memo—Proposed NTP Initiative on Benzidine and Benzidine Congener Dyes, October 31, 1980.

(g) Proposed NTP Initiative on Benzidine and Benzidine Congener Based Azo Dyes, November 24, 1980.

(h) Draft of November 14 Meeting and Protocols for Metabolism Studies.

(i) NIOSH Technical Report "Carcinogenicity and Metabolism of Azo Dyes, Especially Those Derived from Benzidine", DHHS Pub. No. 80-119.

(j) Health Hazard Alert, NIOSH and OSHA Benzidine-, o-Tolidine-, and o-Dianisidine-Based Dyes, DHHS Pub. No. 81-106.

(k) NIOSH Special Occupational Hazard Review for Benzidine-Based Dyes, DHEW Pub. No. 80-109.

(l) Ambient Water Quality Criteria for Benzidine, EPA 440/5-80-023.

(3) Communications before proposal:

(a) Written: Public and Intra-agency or Interagency Memorandum and Comments.

(4) Public comments on the ITC reports.

(5) Reports—published and unpublished data.

(Sec. 4, 90 Stat. 2006 (15 U.S.C. 2603))

Dated: October 31, 1981.

Anne M. Gorsuch,

Administrator.

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